Major Kidney Clinical Research Studies and Projects Inventory

Project to Improve Care in Acute Renal Disease (PICARD)

1. Administrative Data

(a) Name of study/research project and acronym:

Predicting and Improving Outcomes in Acute Renal Failure, or PICARD (Project to Improve Care in Acute Renal Disease)

(b) Type of study/research project (randomized clinical trial, epidemiological study, database, etc.):

Multicenter prospective cohort study of patients with acute renal failure in the ICU

(c) Funding status (currently funded, study/project completed):

Currently funded (No-Cost Extension Period)

(d) Recruitment status (recruitment completed, currently recruiting):

Recruitment completed

(e) For studies/project currently recruiting, indicate total sample size/ number currently enrolled, anticipated period of recruitment:

622 patients with 645 episodes of ARF

(f) Data coordinating center principal investigator contact information (mailing address, phone, fax, e-mail address):

Ravindra L. Mehta, M.D.
University of California, San Diego
200 W. Arbor Dr., #8342
San Diego, CA 92103
Phone: 619-543-7310
Fax: 619-543-7420
E-mail: rmehta@ucsd.edu

(g) Number of recruiting sites, list of principal investigators at recruiting sites, and contact information as in (f) above:

Five sites

Ravindra L. Mehta, M.D. University of California, San Diego 200 W. Arbor Dr., #8342 San Diego, CA 92103 *Phone:* 619-543-7310 *Fax:* 619-543-7420 *E-mail:* rmehta@ucsd.edu	Emil P. Paganini, M.D. Cleveland Clinic, M82 Dept. of Nephrology & Hypertension 9500 Euclid Avenue Cleveland, OH 44195 *Phone:* 216-444-5792 or 216-444-5788 *Fax:* 216-444-7577 *E-mail:* paganie@ccf.org
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T. Alp Ikizler, M.D. Vanderbilt University Medical Center Division of Nephrology Medical Center North S-3223 21st Ave. S. @ Garland Nashville, TN 37232-2372 *Phone:* 615-343-6104 or 615-343-9867 *Fax:* 615-343-4704 *E-mail:* alp.ikizler@mcmail.vanderbilt.edu	

(h) List of Principal Investigators at central laboratories/facilities (identify type of central facility) and contact information as in (f) and (g) above:

Not applicable

(i) Roster of Data and Safety Monitoring Board/Scientific Advisory Committee or other oversight committee(s):

The Observational Study was approved by the Human Subjects Review Committees at e each center.

The Institutional Review Board (IRB) of the University of California, San Diego (UCSD) does not distribute a roster of its members. UCSD has an approved "Assurance of Compliance" on file with the Department of Health and Human Services. The identification number of this Assurance is M1274. This Assurance serves the period of May 7, 1998 through April 30, 2003. A list of the IRB members, by profession and sex, is on file with the federal Department of Health and Human Services.

(j) Private sector support (type of support, e.g., financial, donation of drugs/placebo, etc.):

None

2. Study Design (for completed studies, a copy of the primary publication can substitute for information below)

(a) Objective:

Please see *Appendix A*.

(b) Study design:

Please see *Appendix A*.

(c) Major inclusion criteria:

Please see *Appendix A*.

(d) Major exclusion criteria:

Please see *Appendix A*.

(e) Description of the intervention(s) not applicable:

Please see *Appendix A*.

(f) Baseline/eligibility visit schedule (number of visits, major assessments):

Please see *Appendix A*.

(g) Follow-up contact schedule (frequency, type of visit-phone, in-clinic, major assessments):

Please see *Appendix B.*

(h) Primary outcome, secondary outcomes:

(i) Brief summary of power estimates used to justify sample size/duration, including critical assumptions (i.e. effect size estimates, estimated event rates or rate of change in outcome measure):

(j) Web site:

www.picardtrial.com (private password protected)

3. Data and Biological Sample Resources

(a) Biological samples collected in ongoing studies/research projects (specify the type of sample, e.g., blood, urine, etc., the amount, and the point in the study when samples were collected, e.g., baseline visit #1, baseline visit #2, follow-up visit #1; specify months after randomization/study entry):

Biologic samples were not collected routinely as part of this study except for specific projects at Vanderbilt, Maine and Cleveland sites.

(b) Biological samples currently in storage from completed trials (grid showing sample collection time, type of sample, amount, and number of study participants sample was collected from, and physical location of where the samples are stored):

Not applicable

(c) Brief summary of typical informed consent provisions (template informed consent form acceptable), including major variables in participant consents, if applicable (e.g., "use for other studies or not", "allow genetic studies or not."). Does consent include use of samples in other studies that are not part of the main study?

Informed consent from UCSD attached as *Appendix C.*

(d) Data collected (grid of data collection by time/clinic visit with specificity on the type of information collected, e.g., quality of life with SF-MOS 36, measurement of kidney function by GFR, serum creatinine measurement, etc.)

See Appendix B

(e) Any provisions for distributing resources outside of the study? What is the sharing plan?

Currently we are in the process of data cleaning and initial data mining for PICARD projects.

4. Ancillary Studies

(a) Process and contact person (name, address, phone, fax, and e-mail address) for application to perform ancillary studies:

No ancillary studies at this time

(b) List of ancillary studies approved, completed, and ongoing (including source of funding and amount):

Not applicable

5. List of Publications and Presentations (full citations, also note manuscripts in progress)

Articles:

Mehta RL, Pascual MT, Soroko S, Chertow GM. Diuretics, mortality, and nonrecovery of renal function in acute renal failure. *JAMA*. 2002 Nov 27;288(20):2547-53.

Mehta RL, McDonald B, Gabbai F, Pahl M, Farkas A, Pascual MT, Zhuang S, Kaplan RM, Chertow GM. Nephrology consultation in acute renal failure: does timing matter? *Am J Med*. 2002 Oct 15;113(6):456-61.

Mehta RL, Pascual MT, Gruta CG, Zhuang S, Chertow GM. Refining predictive models in critically ill patients with acute renal failure. *J Am Soc Nephrol*. 2002 May;13(5):1350-7.

Liangos O, Sakiewicz PG, Kanagasundaram NS, Hammel J, Paiouh M, Seifert T, Paganini EP. Dialyzer fiber bundle volume and kinetics of solute removal in continuous venovenous hemodialysis. *Am J Kidney Dis*. 2002 May;39(5):1047-53.

Pannu N, Mehta RL. Mechanical ventilation and renal function: an area for concern? Am *J Kidney Dis*. 2002 Mar;39(3):616-24.

Himmelfarb J, Evanson J, Hakim RM, Freedman S, Shyr Y, Ikizler TA. Urea volume of distribution exceeds total body water in patients with acute renal failure. *Kidney Int.* 2002 Jan;61(1):317-23.

Paganini EP, Kanagasundaram NS, Larive B, Greene T. Prescription of adequate renal replacement in critically ill patients. *Blood Purif*. 2001;19(2)238-44. Review.

Kanagasundaram NS, Larive AB, Paganini EP. A fractional dialysate collection method to estimate solute removal in continuous venovenous hemodialysis. *Kidney Int*. 2000 Dec;58(6):2579-84.

Abstracts:

Greene T, Kanagasurum S, Larive B, and Paganini E for the PICARD Study. Unified Quantification of Hemodialysis (HD) Dose in Non-Steady State Conditions of Acute Renal Failure (ARF). Abstract: 35th Annual Meeting of the American Society of Nephrology, Nov 1-4, 2002.

Mehta RL, Pascual MT, Savage BR, Soroko S, Ikizler TA, Paganini EP, Himmelfarb J and Chertow GM for the PICARD Study. Lower than Expected Mortality Rates in Critically Ill Patients with Acute Renal Failure (ARF): PICARD Experience. Abstract: 35th Annual Meeting of the American Society of Nephrology, Nov 1-4, 2002.

Mehta RL, Pascual MT, Savage BR, Soroko S, Ikizler TA, Paganini EP, Himmelfarb J and Chertow GM for the PICARD group. Sepsis Influences Outcome from Acute Renal Failure (ARF) in Critically Ill Patients. Abstract: 35th Annual Meeting of the American Society of Nephrology, Nov 1-4, 2002.

Garcia M, Seifert T, Larive B, Mehta R, Kanagasundaram NS, Paganini EPP, the PICARD stud group. Weights and Fluid Balance in the ICU ARF Patient: How Do They Compare? Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Chertow GM, Pascual MT, Himmelfarb J, Ikizler TA, Paganini EP, Mehta RL, for the PICARD study. Reasons for Non-Enrollment in a Cohort Study of Acute Renal Failure in the Critically Ill: The PICARD Experience and Implications for a Clinical Trials Network. Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Jahansouz F, Lamott J, Stephanson LG, Mehta RL, for the PICARD Study Group. Pharmacy Cost Analysis of Citrate Anticoagulation (CIT) for Continuous Renal Replacement Therapy (CRRT). Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Mehta RL, Pascual MT, Savage BR, Zhuang S, Ikizler TA, Paganini EP, Himmelfarb J, Chertow GM for the PICARD Study. Spectrum of Acute Renal Failure in the ICU: Preliminary Results from a Multicenter Cohort Study. Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Sharma A, Pascual M, Gruta C, Savage B, Mehta RL, for the PICARD Study Group. Effect of Citrate Anticoagulation (CIT-A) on Acid Base Balance in Continuous Veno-Venous Hemodiafiltration (CVVHDF). Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Mehta RL, Pascual MT, Zhuang S, McDonald BR, Gabbai FB, Pahl MV, for the PICARD Study. Effect of Diuretic Use on Outcomes from Acute Renal Failure (ARF) in

the Intensive Care Unit (ICU). Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Savage BR, Pascual MT, Mehta RL, Gruta CG, Ikizler TA, Himmelfarb J, Paganini E, Chertow GM, for the Project to Improve Care in Acute Renal Disease (PICARD) Study Group. Data Acquisition in a Multicenter Trial of Acute Renal Failure (ARF) Using Optical Character Recognition (OCR). Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Savage BR, Pascual MT, Mehta RL, Ikizler TA, Himmelfarb J, Paganini E, Chertow GM, for the Project to Improve Care in Acute Renal Disease (PICARD) Study Group. Monitoring Clinical Trial Progress: The PICARD Web-Based Auditing and Feedback System. Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Ikizler TA, Hariachar S, Gritter N, Flakoll P, Levenhagen D, Paganini E, Hakim RM, Himmelfarb J, for the PICARD Study Group. Urea Volume of Distribution is Greater than Total Body Water in Acute Renal Failure (ARF) Patients. Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Kanagasundaram NS, Greene T, Larive B, Garcia MA, Daugirdas JT, Depner TA, Paganini EP, The PICARD study group. Dosing Intermittent Hemodialysis (IHD) in the Acute Renal Failure (ARF) Patient – Blood-Side Methods Overestimate Urea Removal. Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Kanagasundaram NS, Greene T, Larive B, Garcia MA, Depner TA, Daugirdas JT, Paganini EP, the PICARD study group. Variability of Intermittent Hemodialysis (IHD) Dose in the ICU Patient with Acute Renal Failure (ARF). Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Kanagasundaram NS, Greene T, Larive B, Garcia MA, Daugirdas JT, Depner TA, Paganini EP, The PICARD Study Group. Estimating Urea Distribution Volume (V) in ICU Patients Receiving Intermittent Hemodialysis (IHD) for Acute Renal Failure (ARF). Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Kanagasundaram NS, Larive B, Garcia MA, Depner TA, Daugirdas JT, Greene T, Paganini EP, the PICARD Study Group. Intermittent Hemodialysis (IHD) in ICU Acute Renal Failure (ARF) –Access Recirculation in Temporary Veno-Venous (VV) Catheters. Abstract: 34th Annual Meeting of the American Society of Nephrology, Oct 13-17, 2001.

Mehta RL, Pascual MT, Gruta CG, Zhuang S, Robertson S, Chertow GM, for the PICARD Study. Refining Predictive Models in Critically Ill Patients with Acute Renal Failure. Abstract: 33rd Annual Meeting of the American Society of Nephrology, Oct 13-16, 2000.

Mehta RL, Pascual MT, Gruta CG, Zhuang S, Robertson S, Chertow GM, for the PICARD Study. Serial Use of Predictive Indices in Acute Renal Failure (ARF): Need for Time-Specific Models? Abstract: 33rd Annual Meeting of the American Society of Nephrology, Oct 13-16, 2000.

Pascual MT, Savage BR, Gruta CG, Mehta RL, for the PICARD Study Group. Development of the PICARD Study Shared Database Management System (SDBMS). Abstract: 33rd Annual Meeting of the American Society of Nephrology, Oct 13-16, 2000.

Mehta RL, Pascual MT, Zhuang S, Chertow GM, for the Project to Improve Care in Acute Renal Disease (PICARD) Collaborative Study Group. Spectrum of Acute Renal Failure (ARF) in the ICU: Patient Characteristics and Outcomes. Abstract: 32nd Annual Meeting of the American Society of Nephrology, Nov 5-8, 1999.

Himmelfarb J, Chaffin M, Knights S, McMonagle E, Ikizler TA, McMenamin E, PICARD Study Group. Plasma Protein Oxidation as a Measure of Oxidant Stress in Patients with Acute Renal Failure (ARF). Abstract: 32nd Annual Meeting of the American Society of Nephrology, Nov 5-8, 1999.

Ikizler TA, Evanson J, Gritter N, Flakoll PJ, Hakim RM, Himmelfarb J, PICARD Study Group. Determination of Total Body Water in Acute Renal Failure (ARF) Patients. Abstract: 32nd Annual Meeting of the American Society of Nephrology, Nov 5-8, 1999.

Manuscripts in progress (selected):

Reasons for Non-Enrollment in a Cohort Study of Acute Renal Failure: PICARD Experience and Implications for a Clinical Trials Network

Spectrum of Acute Renal Failure in the ICU: Results from a Multicenter Cohort Study: The PICARD experience

Nutritional Status Predicts Mortality in Critically Ill Patients with Acute Renal Failure

Unified Quantification of Hemodialysis (HD) Dose in Non-Steady State Conditions of Acute Renal Failure (ARF)

Sepsis Influences Outcome from Acute Renal Failure (ARF) in Critically Ill Patients

Data Acquisition in a Multicenter Trial of Acute Renal Failure (ARF) Using Optical Character Recognition (OCR)

Appendix A. PICARD STUDY DESIGN

Objective

The PICARD project is a collaborative study at 5 centers focused on defining the current pre-dialytic, dialytic, and nutritional management of ICU patients with Acute Renal Failure (ARF) in the ICU and the impact of these interventions on patient outcomes. Each site has used a common data instrument for data capture, and the pooled data resides in a relational database at the PICARD data coordinating center. Additionally each site has focused on one of the following three projects:

- Assess the performance of existing generic and disease-specific severity of illness methods for predicting outcomes in ARF and develop a severity of renal dysfunction scoring system. Determine which process factors influence outcomes from ARF.

- Determine the optimal dialysis dose measurement methodology in IHD and CRRT and develop and validate a unified method of dialysis dose measurement. Characterize the association between dialysis dose and outcome.

- Determine appropriate methods for nutritional assessment, nutritional prescription and delivery. Define the relationship between severity of illness and nutritional status and the effect of dialysis process variables on nutritional status and level of catabolism. Establish the association between nutritional status and outcome

Study Design

- Observational study of the natural history and course of patients consulted for Acute Renal Failure in the ICU at 5 centers in the USA* over a period of 30 months.

- Following informed consent, patients were followed prospectively through their ICU course.

- Data variables were recorded for the first ICU day, for the period of consultation in the ICU, three days preceding the start and three days following the last day of consultation and at hospital discharge.

- Data is pooled from all sites into a centralized database.

**Cleveland Clinic Foundation, Cleveland, OH; Maine Medical Center, Portland, ME; University of California, San Diego Medical Center, San Diego, CA; University of California, San Francisco Medical Center, San Francisco, CA; and Vanderbilt University Medical Center, Nashville, TN.*

Inclusion Criteria

- Age ≥18 years
- Admitted to ICU and Nephrology consultation obtained
- Definition of ARF:

  -New onset ARF with baseline* serum creatinine ≤ 1.4 mg/dl: sustained increase in creatinine ≥ 0.5 mg/dl above baseline

  -ARF on Chronic Renal Insufficiency (CRI) with baseline* serum creatinine ≥ 1.5 up to 4.9 mg/dl: sustained increase in creatinine ≥ 1.0 mg/dl above baseline

  **Baseline Creatinine = value closest to Hospital Admission (within 6 months prior to admission)*

Exclusion Criteria

- Pregnancy
- Prisoners or other institutionalized individuals
- Previous dialysis for acute or chronic renal failure
- Kidney transplantation
- ARF from urinary tract obstruction
- ARF from a volume responsive pre-renal state

Major Outcomes

- Mortality

  — ICU and Hospital

- Renal Functional Recovery

  — *Complete Recovery:*
  New Onset ARF: Serum creatinine < 2.0 or back to 20% of baseline
  Acute on CRI: Serum creatinine within 20% of baseline

  — *Incomplete or No Recovery:*

- Serum creatinine higher than baseline and dialysis discontinued prior to discharge (*incomplete*)
- Dialysis dependent at hospital discharge/death (*no recovery*)

- Length of Stay

  — ICU and Hospital

- Procedure-Related Adverse events

Appendix B

PICARD Database Variables

Data variables were recorded for the first ICU day, for the period of consultation in the ICU, three days preceding the start and three days following the last day of consultation and at hospital discharge. Data is pooled with site identifiers.

Table I: Demographics, Past Medical History, Hospital Admission

•Demographics: Name, Hospital Number, DOB, SS Number, Race, Gender, Marital Status, Test Site/Hospital
•Past Medical History: HTN, DM, COPD, CHF, LEUKEMIA, LYMPHOMA, LIVER DISEASE, HIV, CHEMOTHERAPY, RADIATION THERAPY, STEROIDS, OTHER
•Hospital Admission: Admission Date/Time; ICD-9 Admission Diagnostic Codes

Table II: Hospital Discharge

•Hospital Discharge Date, Number of Codes, Discharge Status: Alive/Dead, DNR: yes/no; ICD-9 Discharge Diagnostic Codes

Table III: ICU Summary Data

•ICU Stay Number, ICU Admission and Discharge Dates
•ICD-9 Admission and Discharge Diagnosis (only for the ICU stay when patient is consulted)

Table IV: Renal Data

•History of CRI, Etiologies of ARF (as defined by PICARD Codes and ICD-9 Codes);
•Determine Eligibility for Enrollment: Increase in Creatinine by 0.5 or 1.0: include date of increase, Urine Output, Fluid Volume Status at time of increase
•Renal Consult Number, Consult Start and End Dates, Consult Start and End Locations
•Start of Dialysis and Reasons for Starting Dialysis
•Type of Renal Outcome and if applicable, Date and Location of Renal Recovery

Table V: Renal Procedures

•General Procedure Type: HD vs. CRRT and Number of Procedure Days
•Start and End Dates of Procedure
•Reasons for any Procedure Crossover

Table VI: Daily Entries: Intake and Output, Illness and Nutrition

•24 hour Intake and Output with special emphasis on Nutritional Parameters and Dialysis-Related Volumes;
•Coding of the Illness Panel Variables looking at the following Organ Systems: Hepatic, Respiratory, Renal, Cardiovascular, Neurological;
•Coding for Sepsis Status: SIRS, Sepsis, Septic Shock
•Daily severity of illness scores (APII, APIII, LODS, SAPS, MODS, Liano, etc.)

Table VII: Daily Labs Chemistry (Serum and Urine), Hematology, Urinalysis, Microbiology

Table VIII: Daily Vital Signs

Including Hemodynamic Parameters and Pressor Data

Table IX: Daily Medications
Diuretics, Antibiotics, etc.

Table X: Hemodialysis Treatment
•One form per treatment: HD-specific labs and weights, Physician UF Orders
•Data on Filters, Solutions, Access, Anticoagulation, Blood and Dialysate Flow Rates, Actual UF removed, Complications, Medications

Table XI: CRRT Treatment
•One form per 24 hours: CRRT-specific labs and weights, Physician UF Orders
•Data on Filters, Solutions, Access, Anticoagulation, Blood/Dialysate/Replacement Fluid Flow Rates, Actual UF removed, Complications, Medications

Appendix C. PICARD Consent Form Sample

UNIVERSITY OF CALIFORNIA SAN DIEGO
CONSENT TO ACT AS A RESEARCH SUBJECT

PREDICTING AND IMPROVING OUTCOMES FROM ACUTE RENAL FAILURE

Institution: University of California, San Diego Medical Center, Hillcrest and Thornton
Principal Investigator: Ravindra L. Mehta, M.D.

INTRODUCTION

Ravindra L. Mehta, M.D. and colleagues are conducting a research study designed to better understand the current management of acute renal failure (ARF), a condition in which the kidneys are damaged and less able to perform their functions of removing waste products and excess fluid from the body. The researchers hope to understand which physical conditions, medications and practice patterns are associated with the best and worst outcomes, including whether or not dialysis (a method of replacing kidney function with a machine) is required. This study is part of a multi-center study in the USA, designed to evaluate the current management of ARF and to develop methods to improve the overall management of this condition. A total of 7 hospitals are participating in this study of which 2 are in San Diego. You have been asked to take part because you are admitted to an ICU and have developed acute renal failure. It is anticipated that there will be approximately 100 to 200 participants at each site every year. The study is expected to last for 4 years starting in February 1999.

DESCRIPTION OF STUDY

Section 1: Observational Study:

If you agree to be in this study, information from your chart will be collected and entered into a database. This will include a review of your medical history, physical examination and routine blood and urine tests which are routinely done to evaluate your underlying condition and the level of renal function. No additional tests or procedures other than those done for routine care and management of critically ill patients with acute renal failure will be done.
Yes _____ No _____

Section 2: Additional Labs and Procedures:

Additionally, the following will happen to you (please circle "yes" or "no" and initial where applicable):

a) A small amount of blood (approximately two tablespoonfuls, 30 ml) once per week for approximately 3 weeks may be drawn for additional tests specific for your kidney function and nutritional status.

You agree to undergo blood and urine sampling related to renal function, dialysis and nutritional status.

Yes _____ No _____

b) You may have an isotope renal scan (DTPA and iothalamate) to evaluate the blood flow going to your kidney and to determine the amount of blood being filtered by the kidneys. This procedure requires the

intravenous (in a vein) or subcutaneous (under the skin) injection of a small amount of radiolabelled substance and collection of blood and urine samples for approximately 12 to 24 hours afterwards. The amount of radiation used is extremely small (approximately equivalent to an x-ray) and does not have any other side effects. You may have this procedure repeated two to three times during your hospital course.

You agree to undergo isotope renal scans to evaluate renal function.

Yes _____ No _____

c) You may have measurements of your body composition and distribution of fluids in your body done by a technique called bioimpedance spectroscopy (BIS). This is a non-invasive device similar to an EKG machine which measures the passage of an extremely small current through the body tissues.

You agree to undergo BIS. Yes _____ No _____

d) You may be asked to complete questionnaires pertaining to your quality of well-being and ability to carry out your daily activities prior to and following your illness. If you have difficulty seeing, someone will assist you in completing the questionnaires. The questionnaire should take 15 to 30 minutes to complete.

You agree to complete the questionnaire. Yes _____ No _____

RISKS AND BENEFITS OF STUDY

Participation in this study may involve some added risks or discomforts to those ordinarily associated with the management of an ICU patient. These are as follows:

1. The amount of radiation you will be exposed to by the isotope renal scans is relatively small (less than 2cGy). This dose could be harmful, but the risk is so small that it is difficult to measure. If you are especially concerned with radiation exposure or you have had a lot of x-rays already, you should discuss this with Dr. Mehta. The substances used for the isotope (iothalamate and DTPA) do not pose any additional risk.

2. Risks associated with taking blood from a vein include: bleeding, a bruise, and the possibility of an infection with swelling, redness, pain, fainting and dizziness. In most instances the blood samples will be drawn from the same needles used for providing IV access.

3. There are no risks associated with the bioimpedance measurements as the technique is similar to performing an electrocardiogram (EKG).

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call (858)534-4520 for more information about this, to inquire about your rights as a research subject, or to report research-related problems.

Neither you nor your insurance company will be billed for any tests which are designated for research purposes only.

There will be no direct benefit to you from entering this study. The investigator, however, may learn more about the management of acute renal failure.

_____ has explained this study to you and answered your questions. If you have other questions or research related problems, you may reach Dr. Mehta at (619) 543-7310.

Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution.

Research records will be kept confidential to the extent provided by law. This information will be recorded in a database which will have pooled data obtained from other centers. The information will be shared with other investigators in the multicenter project for analysis; however, research records will be coded in such a manner as to not identify you by name.

You have received a copy of this consent document to keep and a copy of "The Experimental Subject's Bill of Rights."

You agree to participate.

_____	_____	
Participant	Date	
_____	_____	_____
Patient's Legal Representative	Date	Relationship
_____	_____	_____
Principal Investigator or Representative	Date	Witness